

The article was alleged to be misbranded in that representations on the cartons and in the circulars that it would be efficacious in the treatment of goiter and constipation; would be efficacious for preventing scurvy; would be efficacious in the prevention of all diseases of the thyroid; would maintain resistance of the body to infection; would be efficacious as a stimulant and benefit to the stomach; would have a wonderfully soothing effect in cases of intestinal flu, colds in the throat or lungs; and that physicians would advise the use of the article in all troubles resulting from an insufficient daily supply of iodine, were false and misleading since it would not be efficacious for the said purposes and since physicians would not advise its use in all troubles resulting from an insufficient daily supply of iodine.

On December 20, 1940, a plea of nolo contendere having been entered by the defendant, the court imposed a fine of \$150 on count 1. Imposition of sentence was suspended on count 2 and the defendant was placed on probation for 9 months.

375. Misbranding of World Famous New Life Laxative Tonic. U. S. v. Harry B. Kahng (New Life Laboratories and Oriental New Life Medicine Co.). Tried to a jury. Verdict of guilty. Defendant placed on probation for 1 year. (F. D. C. No. 952. Sample Nos. 5425-D, 82986-D.)

The labeling of this product bore false and misleading representations regarding its composition and its efficacy in the conditions indicated below, and falsely represented that the article contained no harmful or habit-forming drugs.

On June 18, 1940, the United States attorney for the Northern District of Georgia filed an information against Harry B. Kahng, trading as the New Life Laboratories and as the Oriental New Life Medicine Co. at Atlanta, Ga., alleging shipment on or about October 2 and December 7, 1939, from the State of Georgia into the States of Alabama and Florida of quantities of the above-named drug product which was misbranded.

Analyses showed the article contained Epsom salt, free sulfur, senna, anise, cascara, licorice, and unidentified substances.

The article was alleged to be misbranded in that the statements, "New Life * * * System Cleanser and Tonic for Every Member of the Family * * * A Real Remedy for every one," borne on the cartons, were false and misleading in that they represented that it would be efficacious in producing the improvement in health, well-being, and vigor implied in the expression "New Life"; that it would be efficacious as a system cleanser and tonic for every member of the family and was a real remedy for everyone; whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the statements, "Highly recommended for constipation, the usual cause of stomach disorder, kidney, bladder trouble, gas pains, biliousness, thus promoting better health in general and bring resistance to many common diseases," borne on the cartons, were false and misleading in that they represented that constipation is the usual cause of stomach disorders, kidney and bladder troubles, gas pains, and biliousness, and that the article would be efficacious in the prevention of the usual stomach disorders, kidney and bladder troubles, gas pains and biliousness, and would promote better health in general and bring resistance to many common diseases; whereas constipation is not the usual cause of stomach disorders, kidney and bladder troubles, gas pains and biliousness, but said disorders and ailments have many and varied causes, and the article would not be efficacious in prevention of the conditions named in the said statements, would not promote better health in general, and would not bring resistance to many common diseases.

It was alleged to be misbranded further in that the statements, "New Life A preparation of many centuries old world famous Oriental Gen Sen formula. * * * Directions: Take regularly at bed time $\frac{1}{2}$ teaspoonful in $\frac{1}{2}$ glass warm or cold water (stirred well). Regulate dose to bring 2 evacuations of bowels daily by either increase or decrease doses, as some individuals are different than others. Children proportion to the age. If desired, add sugar to improve taste. * * * Known to be highest value of herbal tonic. Contains no harmful or habit forming drugs," borne on the cartons, were false and misleading in that they represented that the article was a preparation of "many centuries old world famous Oriental Gen Sen formula," that it was an herbal tonic and contained no harmful or habit-forming drugs; whereas it was not a preparation of "many centuries old world famous Oriental Gen Sen formula," it was not an herbal tonic since it contained Epsom salts and free sulfur, mineral substances, and contained drugs which when used in the dosage and with the frequency prescribed in the labeling might be harmful and habit-forming.

On October 24, 1940, the defendant having entered a plea of not guilty, the case came on for trial before a jury. The trial was concluded on October 28 on which date the court, after hearing arguments of counsel on behalf of the Government and the defendant, instructed the jury as follows:

UNDERWOOD, *District Judge*. "Gentlemen of the jury, this is an indictment which is not evidence, but merely the charges of the Government brought by the United States against this defendant charging him with the violation of a certain Federal law to which I will direct your attention later.

"To this indictment, the defendant has entered a plea of not guilty and this plea puts the burden upon the Government to prove him guilty of the offense charged beyond a reasonable doubt. Before instructing you with respect to the law governing the particular offense charged in the indictment, there are some general rules of law to which I will call your attention.

"It is the judge's duty to instruct you as to the law of the case, and you must accept the law as given by the court, but you are the sole judges of the facts in the case, the weight of the evidence, and credibility of the witnesses. If the court should express, or you think he has expressed any opinion whatever, with respect to the facts in the case, you are not bound by it, but should follow your own conclusions and make your own finding of fact since I have stated you are the sole judges of the facts. You should take the law as charged by the court and apply it to the evidence and render such verdict that you find the law and the evidence demands.

"The defendant comes into court with the presumption of innocence in his favor, and that presumption remains with him throughout the trial, until he has been shown to be guilty beyond a reasonable doubt of the offense charged in the indictment. This presumption has relation to every fact that must be established in order to prove his guilt beyond a reasonable doubt.

"Reasonable doubt does not mean just any possible doubt that you might have, but it means such reasonable doubt as a careful, prudent, and reasonable man ought to entertain in the circumstances proven. That is, it means reasonable moral certainty that all reasonable doubt of defendant's guilt is excluded by the evidence.

"Now in weighing the evidence in this case, you should consider the circumstantial, as well as the direct testimony, for frequently it is not possible to prove facts by direct testimony. The weight of the evidence and the credibility of the witnesses, as I have stated, what are the force and effect of the facts and circumstances proved in this case are questions solely for your determination.

"In weighing the testimony and the credibility of the witness the jury may, among other things, consider his manner and demeanor on the stand, his feeling, interest, prejudice or bias, if any; his means of knowing what he is testifying to; the probability or improbability of what he testifies to; the consistency or inconsistency of his statements with other facts proved in the case; the reasonableness or unreasonableness of his testimony and also his personal credibility, so far as it may legitimately appear from the trial of the case. The number of witnesses on any contested point may be considered by you, but the truth is not always with the greater number.

"If conflicts in the testimony of witnesses exist, it is your duty to reconcile them without imputing perjury to anyone, if you reasonably can, but if you can't do this reasonably, of course, you will believe the one that you think most worthy of belief.

"Certain expert testimony has been introduced in evidence. You will consider that and treat it in the same manner that you do any other testimony in the case. The simple fact that it was offered by experts does not compel you to take their testimony in preference to any other, but you should give the testimony of expert witnesses the same weight, the same consideration, everything else being equal, as that of other witnesses. That is, give such opinions, and receive of them such weight as you deem them entitled to. Where opinions are given by experts based upon hypothetical questions, you should carefully examine the statement of facts that have been assumed in the question and determine whether or not such facts have been proven, and what the opinion is in the light of what has actually been proven.

"This indictment is in two counts. The first, charging the defendant with violating the Federal Food, Drug, and Cosmetic Act, by introducing into interstate commerce a certain drug known as New Life. It is alleged that the interstate shipment charged in the indictment was made on June 25, 1938, from Atlanta, Ga., to C. W. Barnard, in Birmingham, Ala.

"The second count charges a similar offense on the same day, in the same language except that the interstate shipment was from Atlanta, Ga., to Hugh E. Tuck, Tallahassee, Fla.

"In both counts of the indictment it is charged the misbranding consisted of certain representations on the labels of the drug which the Government maintains were false and misleading.

"First, it is claimed that the following expressions were false and misleading. To wit: New Life * * * System Cleanser and Tonic for every member of the family * * * a real remedy for every one.'

"Second, the Government maintains that the article was further misbranded in that the labels stated the drug was 'highly recommended for constipation, the usual cause of stomach disorder, kidney, bladder trouble, gas pains, biliousness, thus promoting better health in general and bringing resistance to many common diseases.'

"The Government's contention is, while the label literally recommends the drug only for constipation, nevertheless, the immediate association of the category of diseases which the label asserts are usually caused by constipation, was misleading and really amounted to an assertion that the drug was a remedy for such diseases, as well as for constipation.

"The Government further maintains that the statement on the label that the drug was 'a preparation of many centuries old, world famous Oriental Gen Sen formula,' was false and misleading; and that if the preparation was taken as directed on the label, it would be harmful and habit-forming; and further, that the claim that the drug was 'known to be of highest value of herbal tonic, Contains no harmful or habit-forming drug' was false and misleading.

"The defendant, on the other hand, denies all these charges and contends the drug in question was not represented on the label to be anything more than a satisfactory remedy for constipation and that the defense in the case shows that all of its ingredients taken separately, or in the combination indicated, were suitable and helpful in the treatment of constipation and have been used for a great many years by reputable physicians and recognized in the standard pharmacopoeia as suitable for the treatment of constipation, and that there was not a single ingredient that was either harmful or habit-forming; that the preparation is a recognized and satisfactory remedy for constipation and especially valuable for people seeking relief from such trouble who are unable or unwilling to consult physicians and to secure specific treatment and prescriptions from them.

"Defendant further contends there is no evidence to show that this preparation is not an old world famous Gen Sen formula, and, as a matter of fact it is such. I do not recall any evidence produced by the Government that the preparation is not an Oriental formula, but the evidence of the Government was merely that the doctors testifying did not know of any such Oriental formula.

"Of course the burden of proof is on the Government to prove beyond a reasonable doubt the charges in the indictment.

"Defendant further contends that the label does not represent the preparation to be a remedy for stomach disorder, kidney, bladder trouble and so forth, and that the words used would not mislead the general public or anyone purchasing the drug into believing that it was represented to be a remedy for such diseases, but that such purchaser would clearly understand the remedy was recommended for constipation only.

"These contentions raise questions of fact which the Government must prove beyond a reasonable doubt, and as I have said before, you are the sole judges of the facts.

"Now the law provides that a drug or device shall be deemed to be misbranded if its label is false or misleading in any particular, and it is for you to determine from the evidence in this case and instructions given you by the court, whether or not the label on the drug as quoted in the indictment is false or misleading in the sense the term as used in the label, in the terms of misbranding as used in the act, the act itself provides if the article is alleged to be misbranded, it is because the label is misleading. Then in determining whether the label is misleading there should be taken into account, among other things, not only representations made, or suggested by statement, word, design, description, or any combinations thereof, but also the extent to which the label fails to reveal, if there is any such failure, facts material in the light of such representation, or material with respect to consequences which may result from the use of the article to which the label relates, under

the conditions of use prescribed in the label thereof, or under such conditions of use as are customary or usual.

"In determining whether or not the label in question in this case was false and misleading, you must approach the question from the viewpoint of a man of ordinary intelligence who might be suffering from constipation and desirous of being relieved of it. That is, the language used on the label should be given the meaning ordinarily conveyed by it, to whom it is addressed, and if you find beyond a reasonable doubt that the language so construed is false and misleading, then you would have to find the defendant guilty.

"The act seeks to protect those who might be induced to purchase the article by the representation made in the label, and the proper test for the construction of such language is what it means to such persons, and not necessarily to those who are skilled in medicine and medical or pharmaceutical science, capable of making necessary distinctions. Its purposes are to secure purity in foods and drugs; to inform purchasers of what they are buying; to prevent injury to the public health, and to require the manufacturer to be honest in his statements, those resulting from insufficient directions and ambiguity, as well as statements that are false, come within the contemplation of the act.

"Now gentlemen of the jury, if from the evidence in this case and under the instructions that the court has given you, you find this defendant guilty beyond a reasonable doubt of the offense charged in the indictment, then the form of your verdict would be, 'We, the jury, find the defendant guilty.' On the other hand, if you find him not guilty, then the form of your verdict would be, 'We, the jury, find the defendant not guilty.' You may retire."

The jury, after due deliberation, returned a verdict of guilty and the court placed the defendant on probation for 1 year.

SEIZURES

376. Misbranding of Electreat Mechanical Heart. U. S. v. 6 Electreat Mechanical Hearts. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 1736. Sample No. 16222-E.)

The labeling accompanying this device bore false and misleading representations regarding its efficacy in the conditions indicated below.

On April 2, 1940, the United States attorney for the Western District of Missouri filed a libel against six of the above-named devices at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about March 6, 1940, by the Electreat Manufacturing Co. from Peoria, Ill.; and charging that it was misbranded.

Examination showed that the device consisted of dry cells, a small buzzer coil, and various attachments intended to apply electrical currents to the body.

The article was alleged to be misbranded in that statements appearing on the carton and in an accompanying circular and booklet were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes. The respect in which the labeling was false and misleading appears in the opinion of the court.

On May 5, 1940, the Electreat Manufacturing Co. appeared as claimant and on July 18, 1940, filed an answer denying the allegations of misbranding. On February 28, 1941, the case having come on for trial before the court and the evidence having been heard and considered, the court handed down the following opinion sustaining the Government's allegations:

COLLETT, *District Judge*. "On March 6, 1940, six devices called Electreat Mechanical Hearts were mailed in interstate commerce¹ from Peoria, Ill., to Kansas City, Mo., for the purpose of sale at the latter place. The devices were seized by the Government and libel proceedings instituted at Kansas City, Mo., for the purpose of bringing about the destruction of the devices.

"The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (Title 21, Sec. 301 et seq. U. S. C. A.) authorizes the destruction of misbranded devices.² The

¹ "Sec. 321 (b) : The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof * * *."

² "Sec. 334 (a) : Any * * * device * * * that is * * * misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *."